February 11, 2005

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Management Dockets, N/A
Dockets Management Branch
Food and Drug Administration
HFA-305
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: NAS 0; Not Product Specific
Response to FDA Request/Comment: Other
Comments on Use of Color on Pharmaceutical Product Labels, Labeling and Packaging; Public Hearing on March 7, 2005
[Docket No. 2005N-0036]

Dear Sir or Madame:

Please reference the *Federal Register* notice of February 3, 2005 regarding a public hearing and request for comments on 'Use of Color on Pharmaceutical Product Labels, Labeling and Packaging'. We have noted CDER's interest in public dialogue on the current practice of using color in printed product packaging and labeling. We also noted the statements in the *Federal Register* notice that "there is no validated scientific method to corroborate the benefits of using colors" in this fashion and that FDA "does not have a policy pertaining to the use of colors on drug product packaging." We appreciate the opportunity to submit comments for the Center's consideration. GlaxoSmithKline has many years of substantive experience with labeling and packaging of pharmaceutical products. Our comments derive in part from this experience.

The current regulations governing prescription drug labeling and packaging (per 21 CFR 201) are silent with respect to sole use of black and white copy versus incorporation of color. Black and white copy is still most commonly used today and it is fully appropriate for the vast majority of labeling and packaging. To our knowledge, there are no substantive data in the published literature to document deficiencies of black and white copy compared with color copy for prescription drug labeling. However, pharmaceutical manufacturers and reviewing Divisions in CDER have had the regulatory discretion (consistent with the current regulations) to develop packaging and labeling with the use of color in specific situations where (a) there are unique considerations meriting the use of color and (b) all applicable regulatory requirements for format and content of labeling have been met. In this communication we will summarize some of the considerations from our perspective.